510(k) Summary

MAR - 5 2012

Date: 25 January 2012

Sponsor:
SIGNUS Medizintechnik GmbH
Industriestrasse 2
D-63755 Alzenau, GERMANY
Tel. + 49 (0) 6023 9166-136
Fax + 49 (0) 6023 9166-161
Url: http://www.signus-med.de

Contact Person: Joachim Schneider, Quality Management/Regulatory Affairs

Trade Names: KIMBA®, KIMBA® mini, MOBIS®, NOVAL®, SEMIAL®, PEEK TETRIS™ and Titanium TETRIS™ devices

Device Classification Class II

Classification Name: Spinal vertebral body replacement device; Intervertebral fusion device with bone graft, lumbar

Regulation: 888.3060; 888.3080

Device Product Codes: MQP; MAX

Device Description: The basic shape of the KIMBA®, KIMBA® mini, MOBIS®, NOVAL®, SEMIAL®, PEEK TETRIS™ and Titanium TETRIS™ devices is a hollow structural frame. The upper and lower aspects of the implant are open. Surface spikes assist in the positive anchorage and seating of the implant between the vertebral bodies. The device is available in a variety of sizes enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition.

Intended Use: When used as a vertebral body replacement, the MOBIS®, SEMIAL®, and PEEK and Titanium TETRIS® devices are indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation.

When used as a vertebral body replacement, the KIMBA® and KIMBA® mini devices are indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The devices are intended for use as a vertebral body replacement in the lumbar spine (from L1 to L5) and are intended for use with supplemental internal fixation.

When used as an intervertebral fusion device in skeletally mature patients, the KIMBA®, KIMBA® mini, MOBIS®, NOVAL®, SEMIAL®, and PEEK and Titanium TETRIS™ devices are intended for use at one level in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device. The devices are intended for use with a supplemental internal fixation system and with autograft to facilitate fusion.

Materials: The MOBIS®, NOVAL®, SEMIAL® and PEEK TETRIS™ devices are manufactured from polyetheretherketone (PEEK-OPTIMA® LT1, Invibio®) as described by ASTM F2026. Integral marker pins are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136 / ISO 5832-3 or tantalum as described by ASTM F560. The Titanium TETRIS devices are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136 / ISO 5832-3. The KIMBA® and KIMBA® mini devices are manufactured from ENDOLIGN® (Invibio®).

Predicate Devices: Lumbar I/F Cage® (P960025)

Ray TFC™ Device (P950019)

AVS PEEK Spacers (K073470, K082014, K083661 and K090166)

ORIA Natura (K073669)

Technological Characteristics: The KIMBA®, KIMBA® mini, MOBIS®, NOVAL®, SEMIAL®, PEEK TETRIS™ and Titanium TETRIS™ devices possess the same technological characteristics as the predicate devices. These include:

- intended use (as described above),
- basic design (hollow structural frame),
- material (polymer, CFRP and/or titanium alloy), and
- sizes (widths, lengths and heights are within the range(s) offered by the predicate systems).

Therefore the fundamental scientific technology of the KIMBA®, KIMBA® mini, MOBIS®, NOVAL®, SEMIAL®, PEEK TETRIS™ and Titanium TETRIS™ devices is the same as previously cleared devices.

Performance Data: Mechanical testing of the worst case device (PEEK TETRIS) was performed according to ASTM F2077 and included static and dynamic compression and static and dynamic compression shear. In addition, the subsidence properties were evaluated according to ASTM F2267.

The mechanical test results demonstrate that PEEK TETRIS™, and therefore KIMBA®, KIMBA® mini, MOBIS®, NOVAL®, SEMIAL®, and Titanium TETRIS™, perform as well as or better than the predicate devices. Hence these devices are as safe and as effective as the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Signus Medizintechnick GmbH
% BackRoads Consulting, Incorporated
Karen Warden, Ph.D.
8202 Sherman Road
Chesterland, Ohio 44026

MAR - 5 2012

Re: K111792
Trade/Device Name: KIMBA®, KIMBA® mini, MOBIS®, NOVAL™, SEMIAL™, PEEK TETRIS™, and Titanium TETRIS™ devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: January 25, 2012
Received: January 27, 2012

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter Rumm MD MPH DSP CLIN D/R

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K111792

Device Name: **KIMBA®, KIMBA® mini, MOBIS®, NOVAL®, SEMIAL®, PEEK TETRIS™ and Titanium TETRIS™ devices**

Indications for Use:

When used as a vertebral body replacement, the MOBIS®, SEMIAL®, and PEEK and Titanium TETRIS™ devices are indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation.

When used as a vertebral body replacement, the KIMBA® and KIMBA® mini devices are indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The devices are intended for use as a vertebral body replacement in the lumbar spine (from L1 to L5) and are intended for use with supplemental internal fixation.

When used as an intervertebral fusion device in skeletally mature patients, the KIMBA®, KIMBA® mini, MOBIS®, NOVAL®, SEMIAL®, and PEEK and Titanium TETRIS™ devices are intended for use at one level in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device. The devices are intended for use with a supplemental internal fixation system and with autograft to facilitate fusion.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111792